

PATENT COOPERATION TREATY

PCT


INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 31 MAR 2006

WIPO PCT

Applicant's or agent's file reference MAN/TI-MP100786-WO		FOR FURTHER ACTION		See Form PCT/IPEA/416
International application No. PCT/GB2005/000004		International filing date (day/month/year) 05.01.2005	Priority date (day/month/year) 09.01.2004	
International Patent Classification (IPC) or national classification and IPC INV. A61K7/16				
Applicant INEOS SILICAS LIMITED et al.				
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> sent to the applicant and to the International Bureau a total of 4 sheets, as follows:</p> <p><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>				
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>				
Date of submission of the demand 25.10.2005		Date of completion of this report 28.03.2006		
Name and mailing address of the international preliminary examining authority:  European Patent Office - Gitschiner Str. 103 D-10958 Berlin Tel. +49 30 25901 - 0 Fax: +49 30 25901 - 840		Authorized officer Boeker, R Telephone No. +49 30 25901-338		



**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/GB2005/000004

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages

1-14 as originally filed

Claims, Numbers

1-37 received on 25.10.2005 with letter of 24.10.2005

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/GB2005/000004

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	16-21,23-29,34,35
	No: Claims	1-15,22,30-33,36,37
Inventive step (IS)	Yes: Claims	
	No: Claims	1-37
Industrial applicability (IA)	Yes: Claims	1-37
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Re Item V.

- 1 Reference is made to the following documents:

D1 : WO-A-01/94512

D2 : GB-A-2 082 454

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- 2.1. The claims include the characterization of the dentifrice compositions by means of parameters (RDA, PAV, FT₁₀₀).

In general the use of parameters in claims can only exceptionally be accepted, i.e. only when a characterization by other means such as composition, structure, amounts is not possible. This has to be demonstrated by the Applicant.

Parameters cannot be used to disguise novelty with respect to the prior art. Consequently, if the Applicant is of the opinion that Doucil A24 or 4A in the present application show the parameters as mentioned in the claims (eg. weight mean particle size) but Doucil A24 or 4A as mentioned in D1 do not, he should have provided evidence for this allegation (n.b. Doucil A24 and Doucil 4A are commercial products of the present applicant).

- 2.2. Claim 15 is directed to a product (dentifrice). The scope of Claim 15 is not clear since it comprises the process feature "at least a proportion of the alkali metal M **has been exchanged** for one or more other metal moieties".

Such a process feature is not discernable at the final dentifrice. Replacement of this feature by a true product related feature (i.e. definition of M as comprising alkali) could have overcome this objection.

Furthermore the meaning of "other metal moieties" is not clear.

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- 3.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of Claims 1 - 15, 22, 30 - 33, 36, 37 is not new in the sense of Article

33(2) PCT with respect to the document D1 on file.

For the assessment of novelty the entire disclosure of documents will be considered and not only specific examples. Examples are illustrations of some particular embodiments. For a novelty assessment the entire teaching of a document is considered.

Document D1 discloses (see D1: page 7, line 5 - page 8, line 17; examples and claims) dentifrice compositions comprising up to 20 % by weight of a crystalline aluminosilicate. Toothpastes including the aqueous compositions disclosed in claims 1-5 (and 10) are explicitly mentioned on page 7, line 6 of D1.

The aluminosilicate used in the examples of D1 are zeolite Doucil A24 or 4A. These P-type zeolites are falling under the definition of the zeolites as mentioned in the claims of D1. According to D1 (see claim 10) they can be included in dental compositions.

These aluminosilicates are the same as in the present application. Doucil A24 and Doucil 4A are commercial products (of the present applicant!). Average particle sizes and other parameters such as Ca-binding capacity, RDA, PAV etc. are inherent properties of the zeolites. Consequently, the Doucil A24 and 4A mentioned in D1 inevitably will show the same properties (RDA, PAV, Ca binding capacity etc.) as the aluminosilicates of the present application.

D1 is therefore considered as novelty destroying for Claims 1 - 15, 22, 30 - 33, 36, 37.

3.2. Document D2 discloses (see D2: page 1, line 27 - page 2, line 21; page 2, lines 39 - 42; page 3, lines 19 - 28; page 7, lines 5 - 17; examples 1 - 3; claims) dentifrice compositions comprising a crystalline aluminosilicate with an average crystallite size from 0.1 - 0.7 μm . The particle size is thus overlapping with the aluminosilicate particle size of the present application. However, D2 does not mention P-type zeolites.

4. Even if the Applicant were in a position to render the Claims novel with respect to D1,

an inventive step could not be acknowledged.

D2 could then be seen as a valuable starting point for assessing inventive step because D2 discloses dentifrice compositions comprising a crystalline aluminosilicate with an average crystallite size from 0.1 - 0.7 μm .

The technical difference between the disclosure of D2 and an (amended) Claim 1 would presumably be the type of zeolite used in the dentifrice compositions.

The Applicant has however not demonstrated any technical effect with respect to this difference. There is no evidence e.g. in form of comparative data on file for a "lower level of abrasivity" (see application on page 1, line 40) or other advantages.

Consequently, the technical problem with respect to D2 can only be seen in the provision of further dentifrice compositions comprising a crystalline aluminosilicate with a small crystallite size.

A skilled person aiming at solving this problem had an incentive from D1 to use zeolite P, in particular Ducil 24A and 4A since D1 already mentions the usefulness of zeolite P in toothpaste formulations.

Consequently, an inventive step could not be acknowledged for a claim 1 which is novel with respect to the prior art.

Since the applicant has not demonstrated any technical effect linked to the additional technical features included in the dependent Claims, these Claims do not meet the requirements of the PCT in respect of inventive step (Article 33(2) and (3) PCT).